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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Cioca, et al.

Serial No.: 09/838,649 Group Art Unit: 1617

Filed: April 19, 2001 Examiner: Wells, Lauren Q.

For: Stable Antimicrobials in Structured Water

**RESPONSE PURSUANT TO 37 CFR 1.111 - Remarks**

The pending claims of the present invention are rejected for being obvious in view of Cioca et al. (U.S. Patent No. 6,139,855; hereinafter "the '855 reference") and Beerse et al. (U.S. Patent No. 6,217,887). According to the Examiner, because the combination of references teaches a cosmetic composition similar to the present claims, the cosmetic composition must have the property of preserving the cosmetic like that of the present invention. The Examiner reasons that a) a compound and its properties are inseparable, therefore, b) silver must be within the cluster structure because the electropositive charges of silver would interact with the electronegative charges within and without of the cluster structure. Applicants assert that there is no similarity between the antimicrobial agent added to structured water in the prior art and the antimicrobial integrated within the cluster structure of the structured water in the present invention, as amended.

Applicants amend Claim 1 of the present invention to clarify that the active is integrated within the cluster structure of structured water. Support for this amendment is found at page 4, lines 1 to 3 wherein the antimicrobials, ionic silver and potassium sorbate, are described as being integrated in the cluster structure of structured water by feeding a solution of unstructured feed water containing silver ions and potassium sorbate through a device for producing structured water. As previously pointed out by Applicants, the feed water for the present invention is distinct from the feed water to make the '855 structured water. The structured water of the '855 reference is not the same as the structured water of the present invention, as amended, because it does not contain the active integrated within its cluster structures. The present invention, as amended, is the surprising discovery that an antimicrobial agent can be integrated within the cluster structure of I and S water.

According to the Examiner, the '855 reference teaches I and S water characterized by a conductivity and pH within the ranges set forth in the present claims. However, unlike the present invention, the active in the '855 reference is added to I and S water. In Example II, at column 5, lines 36 to 37, of the '855 reference, it is indicated that "[c]affeine is added at a level to a series of different vehicles." Each of the vehicles in Example II is either deionized water or structured water. Therefore, the '855 reference does not teach or suggest that caffeine is added to feed water. A product by process claim differs from another

product by process claim if the starting materials to be processed are separate and distinct from one another. Because I and S water are formed from treated feed water, in the present invention, the antimicrobial is added to feed water composed of deionized water with a particular cluster structure stabilizing ionic component. This is not disclosed by the '855 reference. In the present specification, the feed water for cluster stabilization in the present invention is provided at page 7, lines 16 to 25. The feed water for cluster stabilization in the present invention has a pH of about 6.0 to 6.4 and a C (μS/cm) of about 470 to 520. This is in contrast with the '855 starting water which is taught in Claim 1 of the '855 reference as having a pH of about 7 to 7.5 and 250 to 450 μS/cm. The addition of active agents to structured water as taught in the '855 reference is different than the integration of antimicrobial agents within the cluster structure of structured water as described in the present invention, and therefore, a *prima facie* case of obviousness has not been made.

In rejecting claims under 35 U.S.C. §103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Rijckaert*, 28 USPQ2d 1955, 1956 (CAFC 1993) (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant. *Id.* "A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *Id.*, (citing *In re Bell* , 991 F.2d 781, 782, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) (quoting *In re Rinehart*, 531 F.2d 1048, 1051, 189 USPQ 143, 147 (CCPA 1976)). Since a *prima facie* case of obviousness has not been made, for reasons which are discussed above, the burden of coming forward with evidence or data regarding inherent properties has not shifted to Applicants. However, assuming *arguendo* that a *prima facie* case of obviousness could be made, Applicants submit herewith a Declaration under 37 C.F.R. 1.132 by Mirela Ionita-Manzatu ("the Manzatu Declaration.")

In the Manzatu Declaration, paragraph 8, it is demonstrated that structured water having an antimicrobial agent integrated within the cluster structure of structures water is substantially different than the mere addition of an antimicrobial agent to structured water. To demonstrate this, ionic marker, terbium (Tb), is used to detect its location relative to the cluster structure of structured water by flourescent emission spectral analysis, as noted in paragraph 6 of the Manzatu Declaration. The results of the study are described in paragraph 7, and they show that samples of structured water without the Tb marker (sample 1) and of structured water in solution (i.e., the Tb <u>added</u> to the structured water, sample 3) are substantially different than the sample having structured water prepared according to the present invention (i.e., the Tb <u>integrated</u> within the cluster structure of structured water, sample 2.) The substantial difference is demonstrated by the location of peaks on the spectral curves of each sample. Both samples 1 and 3 had peaks located at about 416 nm. In contrast to these samples, sample 2 of the present invention had a peak at about 369 nm. In

addition, sample 2 exhibited a reduction in peak intensity. Therefore, the Tb marker is shielded from fluorescence by being integrated within the cluster structure of structured water. This finding confirms that structured water of the present invention having the Tb marker integrated in the cluster structure of structured water is not a mere solution of the Tb marker added to structured water. These results correlate with the behavior of the antimicrobial ions integrated within the cluster structure of the structured water of the present invention. Therefore, the antimicrobial agent integrated within the cluster structure of structured water in the present invention is not taught or suggested by the combination of the cited references adding an antimicrobial to structured water.

The other combination of references cited against the present invention is Cioca et al. and Stroud et al., however, the same situation arises when making this combination as does with the previous combination of cited references. Therefore, because the combination of Cioca et al. ("the '855 reference") and Stroud et al. fails to remedy the defect of the primary reference (the '855 reference), Applicants assert that this combination of references also fails to render the present invention obvious. In the '855 reference, biological actives are only added to structured water as separate entities, one being added to the other. Further, there is no teaching or suggestion in the '855 reference of adding the biological active to the feed water having the pH of about 6.0 to 6.4 and a conductivity of about 470 to 520, and treating both the active and the specific feed water to integrate the antimicrobial in the cluster structure of the structured water. Therefore, the '855 reference in combination with any other reference that fails to remedy this defect will not render the present invention, as amended, obvious and a *prima facie* case of obviousness has not been made. However, even if a *prima facie* case of obviousness could be made, the Manzatu Declaration demonstrates that the addition of an antimicrobial agent to structured water is substantially different than the integration of the antimicrobial agent within the cluster structure of structured water. As the claims of the present application are believed to be in condition for allowance, issuance of a Notice of Allowance is respectfully solicited.

Respectfully submitted,

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